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No. 01-1050

IN THE

Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,
Petitioner

v.

BIOVAIL CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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BRIEF AMICI CURIAE OF GRAY PANTHERS PROJECT FUND, ET AL. IN SUPPORT OF THE PETITION FOR WRIT OF CERTIORARI AND MOTION TO FILE BRIEF

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MOTION TO FILE

Pursuant to Supreme Court Rule 37.2(b), amici Gray Panthers Project Fund[1], along with Aging Resource Center for Douglas County, Wisconsin, California Citizens for Health Freedom, California Consumer Health Care Council, Charleston County Office of Veterans Affairs, Chinatown Senior Citizen Service Center, Coalition for Consumer Justice, Council of Senior Tyler Countians, Council on Aging Silicon Valley, Defenders Food Co-Op and Resource Center, Delaware State Council of Senior Citizens, Erie County Senior Services, Florence E. Smith Senior Service Center, Friendly Health Services, Good Shepherd Community Center, Gray Panthers of South Dade, Health Care for All, Highland Valley Elder Services, Justice for All, Lafayette Council on Aging, Metro New York Health Care for All, Mid County Senior Center, Pennsylvania Alliance for Retired Americans, RSVP of Natchitoches Parish, Louisiana, Sabine Council on Aging, Seniors for Action, Shalom Senior Center, Southeast Focal Point/Joseph Meyerhoff Senior Center, St. Martin Council on Aging, St. Mary Council on Aging, The Humanitarian Society, Tri-County Independent Living Center, Union Council on Aging, United Senior Action of Indiana, Universal Health Care Action Network, Upper Cumberland Area Agency on Aging, Utica Citizens in Action, Wisconsin Association of Aging Unit Directors, Woodbury County Community Action Agency, Yates County Office for the Aging, and York Senior Center move for leave to file the attached amici curiae brief in support of the Petitioner for the reasons set forth in the brief below. Petitioner has consented to the filing of this brief, but Respondent has not provided consent. The Court will hear the views of the Petitioner and Respondent, who are generic

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1 No counsel for a party authored this brief in whole or in part. No person or entity, other than amici curiae made a monetary contribution to the preparation or submission of this brief.

drug manufacturers. Amici seek leave to file the accompanying brief in order to provide the perspective of the consumer, including senior citizens, who are adversely affected by the decision below.

I. INTERESTS OF AMICI CURIAE.

Amici are a coalition of advocates for consumers and the elderly. Gray Panthers Project Fund is an intergenerational advocacy organization working for social and economic justice. The Gray Panthers' issues include universal health care, jobs with a living wage and the right to organize, preservation of Social Security, affordable housing, access to quality education, economic justice, environment, peace and challenging ageism, sexism, and racism. Aging Resource Center for Douglas County provides meals and other social services to senior residents of Douglas County, Wisconsin. California Citizens for Health Freedom is a grassroots advocacy organization committed to protecting and expanding consumer natural health choices. California Consumer Health Care Council is a grassroots, volunteer-governed and operated organization committed to establishing and enhancing health care systems that work well for all Californians - systems that are safe, fair, accountable, and that promote quality, accessibility, and affordability. Charleston County Office of Veterans Affairs provides social services and health care to veterans. Chinatown Senior Citizen Service Center provides social services and meals to seniors. Coalition for Consumer Justice advocates for universal health care. Council of Senior Tyler Countians provides social services and meals to seniors. Council on Aging Silicon Valley provides a wide range of health and supportive services to older residents. Defenders Food Co-Op and Resource Center provides food to low-income residents. Delaware State Council of Senior Citizens advocates for the health and well being of seniors.

Erie County Senior Services provides services to seniors and represents the needs, interests and concerns of older persons to public officials and others. Florence E. Smith Senior Service Center provides meals, activities and social services to seniors. Friendly Health Services provides medical assistance and supervision for adults with medical or mental health disabilities. Good Shepherd Community Center provides meals, activities and social services to seniors. Gray Panthers of South Dade is a social and economic advocacy group. Health Care for All is a coalition formed to sustain grassroots pressure for universal health care. Highland Valley Elder Services develops and delivers quality and cost-effective services to seniors and assures a network of coordinated, quality, and comprehensive local service delivery systems. Justice For All defends and advances disability rights with national and state-based groups. Lafayette Council on Aging provides social services, activities, and meals to seniors. Metro New York Health Care for All Campaign advocates extending a program of no- or low-cost health insurance coverage to more working, low-income New Yorkers and achieving universal health care. Mid County Senior Center is a multi-purpose senior center that offers meals and recreational and social activities. Pennsylvania Alliance for Retired Americans is a nonprofit organization of retired Americans launched in January 2001 by a national coalition of AFL-CIO affiliated unions and community-based organizations dedicated to economic and social justice. RSVP of Natchitoches Parish recruits, supports, and provides volunteer opportunities and experiences for persons over 55 years of age. Sabine Council on Aging provides meals, activities and social services to seniors. Seniors for Action focuses political energy of seniors in the San Fernando Valley toward reforms that increase access to affordable health care and other objectives. Shalom Senior Center offers social and supportive services to

enhance the lives of older Washingtonians and the homeless. Southeast Focal Point/Joseph Meyerhoff Senior Center, St. Martin Council on Aging, and St. Mary Council on Aging provide meals, activities and social services to seniors. The Humanitarian Society is a volunteer organization that organizes activities to raise funds for the benefit of various local organizations and individuals or families in need. Tri-County Independent Living Center promotes a philosophy of consumer control, peer support, self-help, self-determination, equal access, and individual and systems advocacy, in order to maximize leadership, empowerment, independence and productivity and to support full inclusion and integration of individuals with disabilities into the mainstream of American society. Union Council on Aging provides social services, activities and meals to seniors. United Senior Action of Indiana advocates for seniors on health care issues. Universal Health-Care Action Network brings together diverse groups and activists working for comprehensive health care for all in state and national campaigns across the country. Upper Cumberland Area Agency on Aging provides social services, activities and meals to seniors. Utica Citizens in Action is a regional public policy and citizen advocacy group committed to economic and social justice. Wisconsin Association of Aging Unit Directors, Woodbury County Community Action Agency, Yates County Office for the Aging, and York Senior Center provides social services, activities and meals to seniors.

Amici file this brief to highlight the critical public policy concerns implicated by the decision of the Court of Appeals for the District of Columbia Circuit.

II. INTRODUCTION.

The pro-competitive effect of settling legitimate pharmaceutical patent litigation is threatened by the Court of

Appeals' decision below. In this case, Andrx Pharmaceuticals, Inc. (Andrx), a generic drug manufacturer, and Hoechst Marion Roussel, Inc. (HMRI), the manufacturer of a pioneer drug, attempted to settle potentially devastating patent litigation in the course of complying with the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Act, a statute designed to balance the interests of both the intellectual property rights of pharmaceutical patent holders and the interests of manufacturers of bio-equivalent drugs who seek to bring lower priced generics to the market.

Generic drugs are generally sold for significantly less than brand name drugs. *See United States v. Generix Drug Corp.*, 460 U.S. 453, 454-55 n. 1(1983). A Congressional Budget Office report estimated that consumers saved eight to ten billion dollars in 1994 by purchasing generic drugs. Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998). Amici are concerned with consumers' and seniors' ability to obtain generic drugs. In order to promote the quick introduction of generics to the market, the Hatch-Waxman Act provides a market incentive to the first generic manufacturer to develop a generic drug.

The manufacturer of a brand name drug must file with the United States Food and Drug Administration ("FDA") a costly New Drug Application proving the safety and efficacy of the drug. 21 U.S.C. 355(a). A generic manufacturer may file an Abbreviated New Drug Application ("ANDA"), relying on the proof set forth in the brand name NDA. 21 U.S.C. 355(j)(2)(a). If the brand drug is patented, the generic applicant must certify that its product does not infringe a patent or that the patent at issue is invalid. 21 U.S.C. 355(j)(2)(A)(vii). Once this certification is made, the

brand manufacturer has forty-five days to file patent infringement litigation. 21 U.S.C. 271(e)(2); 21 U.S.C. 355(j)(5)(B)(iii). The FDA may not grant the ANDA until the sooner of thirty months or completion of the litigation. The first ANDA filer, however, receives an 180 day exclusivity period in which to market its generic. 21 U.S.C. 355(j)(5)(B)(iv). The exclusivity period runs from the date the court rules on the patent litigation or when the generic manufacturer begins marketing the drug. *Id.* The generic manufacturer may bring the product to market once it receives FDA approval, or it may await conclusion of the patent litigation.

In the context of this statutory scheme, Andrx developed a generic version of HMRI's successful Cardizem CD and filed an ANDA with the FDA. HMRI sued Andrx for patent infringement in the United States District Court for the Southern District of Florida. The FDA tentatively approved Andrx's ANDA while the litigation was pending. Thereafter, because the patent litigation had not yet concluded, HMRI threatened to file a preliminary injunction suit once the thirty-month period expired. The granting of such an injunction might have triggered the exclusivity period, despite the fact that Andrx would be unable to market the drug by court order. Under these circumstances, no generic manufacturer would be able to market its product during the exclusivity period, and consumers would suffer.

In the face of this high stakes dispute, the parties entered a stipulation that eventually aided Andrx to bring its product to market, thereby ensuring that the public would have access to lower priced drugs and competition in the marketplace. Andrx and HMRI entered into a stipulation in which Andrx promised to maintain the status quo until the patent litigation was settled. HMRI in turn promised not file additional patent infringement suits that would lead to

additional thirty-month delays in the introduction of the generic competitor. HMRI also agreed that Andrx was the first company to file an application with the FDA for a generic version of Cardizem CD. The parties also reached a financial settlement that was contingent on the outcome of the patent litigation, involving quarterly payments from HMRI to Andrx, and a license to Andrx in the event Andrx lost the patent litigation or the litigation continued beyond 1999.

Biovail Corporation ("Biovail"), another generic manufacturer of Cardizem CD, challenged the agreement under Sections 1 and 2 of the Sherman Act, even though Biovail had not received FDA approval for its product at the time of filing its suit and did not allege that it was prepared to market a generic version of Cardizem CD. The United States District Court for the District of Columbia dismissed the claim on the grounds that Biovail could not plead antitrust injury. *Andrx Pharm., Inc. v. Friedman*, 83 F. Supp.2d 179, 184-86 (D.D.C. 2000). The Court of Appeals for the District of Columbia reversed and remanded. *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001). The Court of Appeals' decision means that a generic manufacturer seeking to reduce the risk of treble damage patent litigation and to bring its product to market will have to contemplate treble antitrust damages as well. This threat will make such pro-competitive settlements vastly less likely. The result will be to discourage manufacturers from developing and marketing generic drugs. Consumers and seniors will suffer as a result of the lack of available generics and competition for brand name drugs.

III. SUMMARY OF ARGUMENT.

The Supreme Court should grant Andrx's Petition for Certiorari to insure that the mistaken conclusions of the

Court of Appeals for the District of Columbia Circuit do not prohibit other settlements in the context of the Hatch-Waxman Act that are necessary to bring generics to the market faster. In addition, generic manufacturers should have the ability to settle potentially devastating multiple-front treble damage patent infringement suits without fear of treble damage antitrust suits from competitors that have suffered no injury.

IV. ARGUMENT.

The questions presented in the petition are of great importance to consumers, and the Supreme Court should grant certiorari to correct the Court of Appeals improper decision regarding antitrust injury, antitrust standing, and permissible settlements in the context of the Hatch-Waxman Act. There are four reasons of importance to consumers.

1. Andrx & HMRI entered into an agreement that brought the generic product to the market more quickly, thereby benefiting consumers.

The most critical benefit of the Andrx/HMRI settlement was that Andrx was able to bring a generic product to the market quickly. The research shows that the first generic to enter the market typically charges less than eighty per cent of the brand manufacturer's price. Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998).

Thus, the settlement was of obvious benefit to price sensitive consumers. In the context of a patent infringement case, a generic manufacturer has the right and the incentive under the Hatch-Waxman Act to refrain from placing its drug on the market until the litigation is resolved. Here, Andrx was able to place its product on the market in June, 1999,

despite the fact that the underlying patent litigation was otherwise far from resolution, and thereby to benefit consumers, because it received payments from HMRI and alleviated the threat of continuous litigation.

Each party to the agreement merely calculated the risks of losing the litigation against the benefits of winning. If HMRI was correct that Andrx's product infringed its patent, HMRI was legally entitled to its profit. Under the settlement, part of that profit went to a generic manufacturer, enabling the generic to become a better competitor. Furthermore, under the stipulation, Andrx had the right to license HMRI's product if it lost the patent litigation, or the litigation continued beyond 1999. The settlement therefore brought a generic drug to market without the risk that the manufacturer would file for bankruptcy. The presence of a generic drug on the marketplace greatly benefited consumers and seniors.

2. The settlement was necessary to prevent HMRI from instigating additional litigation, which had the potential to bankrupt Andrx and further delay the introduction of generics to the market.

The Court of Appeals characterized the fact that as part of the settlement, HMRI agreed to pay Andrx $40 million a year during the patent litigation period to compensate Andrx for not prematurely introducing its version of the drug as evidence that Andrx would have placed its product on the market in the absence of a settlement. This payment, however, is substantially less than Andrx could have earned if it introduced its generic product before the litigation was settled. This greater income would have come with greater risk. If Andrx introduced its product before the litigation concluded, Andrx faced the threat of bankruptcy from patent litigation and patent infringement damages. Damages in a patent infringement case are measured by the lost profits of

the brand manufacturer, which are greater than the generic's likely profits, by definition. In addition, patent damages may be trebled.

Andrx entered into the agreement, which was disclosed to the public, to avoid the possibility that it would have to pay hundreds of millions of dollars in damages to HMRI if it marketed its generic and then lost the patent lawsuit. Generic manufacturers routinely await resolution of such lawsuits to avoid damages that threaten to destroy their businesses. Patent litigation can take years to resolve and, in the meantime, the brand manufacturer can maintain and enhance its monopoly. Such delays are not beneficial to price sensitive consumers. Andrx entered into a settlement that permitted it to make income without substantial risk. As a result, it was able to bring its generic product to the marketplace and consumers benefited.

3. The agreement between Andrx and HMRI, which was fully disclosed to the public, did not keep any drug from getting to the market.

Although Biovail filed suit for antitrust damages, it had neither received approval from the FDA to market its drug, instigated litigation against HMRI to seek a declaration that its generic did not infringe HMRI's patent, nor petitioned the FDA for relief on the grounds that Andrx was not actively pursuing approval of its ANDA. As a result, the agreement did not prevent Biovail, or any other manufacturer from placing a bio-equivalent drug on the market. The law is clear that to plead antitrust injury, plaintiff must allege "injury of the type the antitrust laws were intended to prevent." *Brunswick Corp. v. Pueblo Bowl-O-Matic, Inc.*, 429 U.S. 477, 489 (1977). Even if Biovail did suffer injury, it was as a result of the idiosyncrasies of the Hatch-Waxman Act, rather than any act of Andrx or HMRI.

On several occasions, courts and regulatory agencies have stated that Biovail's claims that consumers were hurt by the agreement between Andrx and HMRI are insupportable. For example, after a thorough investigation, the Federal Trade Commission found that "it does not appear that there was any delay in the entry into the market of a generic version of Cardizem CD by Andrx or any other potential manufacturer, or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD." *In re Hoescht Marion Roussel, Inc.*, 66 Fed. Reg. 18636 (April 10, 2001) (proposed consent order). Likewise, the District Court properly concluded that Biovail suffered no injury as a result of the Andrx/HMRI agreement because Biovail was not ready to go to market with a generic version of Cardizem. *Andrx*, 83 F. Supp.2d at 184. The District Court also properly ruled that any alleged harm suffered by Biovail was too speculative to support recovery. *Id.* at 186. A competitor simply should not be permitted to profit by claiming speculative damages that resulted, if at all, from the effects of a complicated federal regulatory scheme. *See, e.g.*, *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 267-68 (3d Cir. 1998). In such cases the competitor's claim causes harm to the consumer.

4. Biovail's claim for damages causes additional barriers to Andrx's entry into the marketplace with generic drugs.

At the time the stipulation was entered into, Andrx faced a real threat that its proposed generic version of Cardizem CD violated a valid patent. The parties were engaged in active litigation to resolve the patent claims. Subsequently, the FDA approved the Andrx product for marketing with the patent infringement lawsuit still pending. Because both companies faced substantial risk if the infringing Andrx product was marketed, the stipulation was intended to allow both companies to reduce the risks they faced as they litigated the case to its conclusion. Consumers benefit from such agreements because they permit generic manufacturers to resolve patent litigation, without risking bankruptcy, while preserving the incentive to develop generics.

The threat of patent litigation was the immediate barrier to Andrx's entry to the market. The settlement of the litigation removed that barrier. Biovail was free to engage in litigation with HMRI or the FDA to accelerate the process. Instead, Biovail attempted to impose another barrier to entry to Andrx, by filing suit for treble antitrust damages. Under the Hatch-Waxman Act, Andrx had taken the risk to become the first generic to file an ANDA and therefore was entitled to the statutory benefit. Biovail's actions threaten the ability of generic manufacturers to bring cheaper drugs to the market, by imposing additional barriers to entry.

V. CONCLUSION.

Amici believe that the agreement at issue implicates matters of significant concern for the general public. The Supreme Court's decision in this area will have a significant impact upon the ability of generic drug makers to bring their low-cost products to market in a timely manner, without the

threat of disabling patent infringement litigation on multiple fronts. The decision of the Court of Appeals for the District of Columbia Circuit is incorrect for the reasons set forth above and would impose additional burdens on consumers and on the elderly. Therefore, Amici respectfully request that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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